Message Text

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PAGE 01 STATE 151917
ORIGIN HEW-06

INFO OCT-01 EA-09 ISO-00 OES-07 SNM-02 /025 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: RBUHRICH, M.D.
EA/ANP:HNELSON (INFO)
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P 292302Z JUN 77
FM SECSTATE WASHDC
TO AMEMBASSY CANBERRA PRIORITY

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E.O. 11652: N/A

TAGS: SWEL, SNAR, TBIO, AS

SUBJECT: U.S. CONTROLS ON THE SALE OF COMPOUND ANAL-
GESICS

REF: CANBERRA 4113

1. FDA ADVISES THAT SECTION 503(B)(1) OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT STATES IN ESSENCE THAT A DRUG INTENDED FOR USE BY MAN MUST BE SOLD OVER-THE-COUNTER (OTC) UNLESS: (A) IS A HABIT-FORMING DRUG TO WHICH SECTION 502(D) APPLIES OR; (B) BECAUSE OF ITS TOXICITY OR OTHER POTENTIAL-ITY FOR HARMFUL EFFECT OR THE METHOD OF ITS USE, OR THE COLLATERAL MEASURES NECESSARY TO ITS USE, IS NOT SAFE EXCEPT UNDER THE SUPERVISION OF A PRACTITIONER LICENSED BY LAW TO ADMINISTER SUCH A DRUG; OR (C) IS LIMITED BY AN APPROVED APPLICATION UNDER SECTION 505 TO USE UNDER THE PROFESSIONAL SUPERVISION OF A PRACTITIONER LICENSED BY LAW TO ADMINISTER SUCH A DRUG; ....

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2. ALL OTC INTERNAL ANALGESICS WERE REVIEWED BY THE OTC INTERNAL ANALGESIC PANEL. THEIR REPORT WILL BE PUBLISHED

IN THE FEDERAL REGISTER ON OR ABOUT 8 JULY 1977. A BRIEF SUMMARY OF THEIR REPORT IS AS FOLLOWS:

THE FOLLOWING SINGLE INGREDIENTS WERE CLASSIFIED AS SAFE

AND EFFECTIVE FOR OTC USE. (CATEGORY I)

ACETAMINOPHEN (PARACETAMOL)
ASPIRIN
CALCIUM CARBASPIRIN
CHOLINE SALICYLATE
MAGNESIUM SALICYLATE
SODIUM SALICYLATE

COMBINATIONS MAY INCLUDE ANY 2 OF THOSE INGREDIENTS AT THE MINIMUM EFFECTIVE DOSE EACH - THAT IS 325 MG FOR ASPIRIN, ACETAMINOPHEN, ETC.

THE FOLLOWING INGREDIENTS ARE CLASSIFIED NOT SAFE AND/OR EFFECTIVE FOR OTC USE. (CATEGORY II)

ACETANILID
CODEINE
IODOPYRINE
PHENACETIN
QUININE

IF THE AGENCY AGREES WITH THE RECOMMENDATIONS OF THE PANEL THESE INGREDIENTS WILL HAVE TO BE REMOVED FROM OTC DRUGS SIX MONTHS AFTER PUBLICATION OF THE FINAL MONOGRAPH.

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THE FOLLOWING INGREDIENTS WERE NOT CLASSIFIED PENDING RECEIPT OF ADDITIONAL DATA. (CATEGORY III)

ALUMINUM ASPIRIN
ANTIPYRINE
SALICYLAMIDE
SALSALATE

THERE WILL BE A 3 YEAR PERIOD FOLLOWING PUBLICATION OF THE FINAL MONOGRAPH IN WHICH STUDIES TO ELICIT THE ADDITIONAL INFORMATION MAY BE PERFORMED. AT THE END OF THE 3 YEAR PERIOD THERE MUST BE ADEQUATE INFORMATION TO DETERMINE THAT THESE INGREDIENTS ARE SAFE AND EFFECTIVE FOR OTC USE OR THE INGREDIENTS WILL HAVE TO BE REMOVED FROM OTC DRUG PRODUCTS.

THIS 3 YEAR TIME LIMIT ALSO APPLIES TO ALL COMBINATIONS CONTAINING ONE OF THESE INGREDIENTS, OR TO ANY COMBINATION CONTAINING MORE THAN 2 INGREDIENTS LISTED IN THE SAFE AND EFFECTIVE GROUP I ABOVE.

THE PANEL HAS FURTHER BEEN UNABLE TO CLASSIFY THE FOLLOW-

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ING INGREDIENTS WHICH IT CALLED ANALGESIC ADJUVANTS:

CAFFEINE
METHAPYRILENE FUMARATE
PHENIRAMINE MALEATE
PHENYLTOLOXAMINE
PYRILAMINE MALEATE
SALICYLAMIDE

DRUG PRODUCT CONTAINING ONE OR MORE OF THESE INGREDIENTS
WILL ALSO COME UNDER THE 3 YEAR TESTING TIME LIMIT.

3. A COPY OF FEDERAL REGISTER PUBLICATION WILL BE SENT
TO EMBASSY AS SOON AS AVAILABLE. CHRISTOPHER
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Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: SALES, DRUGS, POLICIES
Control Number: n/a
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Sent Date: 29-Jun-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
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Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770233-0287
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t1977066/aaaaaerq.tel
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Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
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Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 77 CANBERRA 4113
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 19-Oct-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2159888
Secure: OPEN
Status: NATIVE
Subject: U.S. CONTROLS ON THE SALE OF COMPOUND ANAL- GESICS
TAGS: SWEL, SNAR, TBIO, AS
To: CANBERRA
Type: TE
vdkvgwkey: odbc://SAS/SAS.dbo.SAS_Docs/abcd417d-c288-dd11-92da-001cc4696bcc
Review Markings:
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